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21 June 1999

Dockets Management Branch (HFA-305)  
FDA rm 1061  
5630 Fishers Lane,  
Rockville MD 20852

Subject: Additional Comment on Proposed Amendment

Ref: Docket No. 93N-0044

A statement in the Background section of the preamble to the proposed amendments implies changes to the Human Access definition to allow access for Class II energy to be determined by whether the configuration allows a direct eye exposure to occur (as opposed to the current requirement that determines access to that class level by any part of the human body). The proposed definition b(14) in the text does not include any such relaxation, and it is recommended that this be added to the amendment.

If you need any clarification on this comment, please contact the undersigned.

Yours truly,

Bob Weiner

cc: Jerome Dennis (HFZ-312)  
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93N-0044

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